



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 17, 2016

WTFN – dba Classic Erotica/Holiday Products
% Louie Goryoka
Regulatory Consultant
Med-Device Consulting, Inc.
5804 Rainbow Hill Road
Agoura Hills, CA 91301

Re: K161385
Trade/Device Name: Just Like Me Personal Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: May 12, 2016
Received: May 19, 2016

Dear Louie Goryoka,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K161385

Device Name

Just Like Me Personal Lubricant

Indications for Use (Describe)

Just like Personal Lubricant is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural latex, polyisoprene, and polyurethane condoms.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY
Just Like Me Personal Lubricant

Company Name: WTFN - dba Classic Erotica
Company Address: 20950 Lassen Street
Chatsworth, California 91311

Contact Person: Med-Device Consulting Inc.
Louie Goryoka – Regulatory Consultant
Phone 1 (818) 735-0488
mdci@m-dci.us

Summary Preparation Date: August 16, 2016

Device Trade Name: Just Like Me Personal Lubricant
Common Name: Personal Lubricant
Classification Name(s): Condom
Classification Regulation: 21 CFR §884.5300, Class II
Device Code: NUC
Advisory Panel: Obstetrics and Gynecology
Predicate Devices: Love Liquid® Personal Lubricant
510(k) number K152168

Device Description

The Just Like Me Personal Lubricant is a non-sterile, water based, over-the-counter personal lubricant formulated to be a clear, non-irritating, non-greasy, odorless liquid.

The proposed device contains a blend of ingredients similar to ingredients found in the predicate device.

The device is designed to supplement the body's own natural lubrication fluids and is compatible for use with or without natural rubber latex, polyisoprene, and polyurethane condoms during intimate sexual activity as evidenced by condom compatibility testing.

Indication for Use Statement

The Just Like Me Personal Lubricant is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural latex, polyisoprene, and polyurethane condoms.

Technological Characteristics

The Just Like Me Personal Lubricant has the same intended use as the predicate device.

The Just Like Me Personal Lubricant has similar technological characteristics to the predicate device. It contains ingredients that are similar to those found in the predicate device.

510(K) SUMMARY
Just Like Me Personal Lubricant**Performance Data****Biocompatibility**

The device contact duration with the user is A-limited <24 hours, in accordance with ISO 10993.

Biocompatibility testing was performed in accordance with ISO 10993. The results demonstrate that the device is safe for its intended use.

Test Performed	Results
Cytotoxicity (Direct Contact)	Product is Non-toxic
ISO GUINEA PIG MAXIMIZATION SENSITIZATION TEST- (Method for Liquid Test Articles)	Product does not elicit a sensitization response
Vaginal Mucosa Irritation with Histopathology	Product is considered a non-irritant to vaginal tissue
Acute Systemic Toxicity	There is no evidence of system toxicity

Condom Compatibility

Compatibility Testing was performed in accordance with ASTM D7661-10; "Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms" on three marketed brands of Natural Rubber Latex condoms, one brand of Polyisoprene condoms, and one brand of Polyurethane condoms.

This product is compatible with natural rubber latex, polyisoprene, and polyurethane condoms as demonstrated by the condom compatibility testing.

Shelf Life Testing

The Just Like Me Personal Lubricant has a 2-years shelf life based on the results of an accelerated aging study. The accelerated aging study evaluated the single version of packaging (3.8 oz.) 4 oz. packaging. Following aging, the product met its specifications for viscosity, specific gravity, appearance, color, odor passed the testing, Preservative Effectiveness and Antimicrobial Effectiveness Testing based on USP <51>, Total Microbial Aerobic Count (TAMC) and Total Yeast and Mold Count (TYMC) based on USP <61>, and Absence of Pathogenic organism based on USP <62>.

Conclusion

The results of performance testing demonstrate that the Just Like Me Personal Lubricant is substantially equivalent to predicate devices.